

FORM APPROVED
OMB NO. 0579-0036

OCT 27 2005

(AUG 91)

Qazh

Column E Explanation

This form is intended as an aid to completing the Column E explanation. It is not an official form and its use is voluntary. Names, addresses, protocols, veterinary care programs, and the like, are not required as part of an explanation. A Column E explanation must be written so as to be understood by lay persons as well as scientists.

1. Registration Number: 55-R-0109

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2. Number 1500 of animals used in this study.

3. Species (common name) Guinea pigs of animals used in the study.

4. Explain the procedure producing pain and/or distress.

a. Diphtheria potency - To determine the anti-diphtheria potency of intramuscular and intravenous products using neutralization methodology.

b. Tetanus potency - To quantitate the potency of Tetanus Immune Globulin (Human) by using neutralization methodology.

5. Provide scientific justification why pain and/or distress could not be relieved. State methods or means used to determine that pain and/or distress relief would interfere with test results. (For Federally mandated testing, see Item 6 below)

This testing is mandated by Bayer Product License Testing Requirements. Administration of anesthetic, analgesic or tranquilizer drugs could interfere with the outcome of the testing.

6. What, if any, federal regulations require this procedure? Cite the agency, the code of Federal Regulations (CFR) title number and the specific section number (e.g., APHIS, 9 CFR 113.102):

Agency FDA CFR 21 CFR 640.100